

Remarks

Claims 2-6, 25, 27-33, 35, 36, and 77-89 are pending, of which claims 27-33, 35, 36, and 82-89 have been withdrawn from consideration. Claims 2, 5, 25, and 81 are amended. Withdrawn claims 33 and 36 are amended to parallel the scope of the examined claims. Claims 6, 77-79, and 89 are canceled.

Applicants believe that no new matter has been added by these amendments. Applicants reserve the right to pursue any removed subject matter in a related application. After entry of this amendment, **claims 2-5, 25, 27-33, 35, 36, and 80-88 are pending** (of which claims 27-33, 35, 36, and 82-88 are withdrawn). Reconsideration of the pending claims is respectfully requested.

Election/Restriction

Applicants acknowledge that claims 82-89, submitted with the Amendment and Response on February 11, 2008, are directed to a non-elected invention and are withdrawn from consideration.

Withdrawal of Rejections

Applicants thank Examiner Archie for withdrawing the rejection of claim 1 under 35 U.S.C. §102(b).

Status of the Claims/Claim Objections

The Office action states that claims 3-4 and 80 are objected to as allegedly “dependent from a base claim.” Applicants believe that the Office action meant to state that these claims are objected to for depending from a “rejected” base claim. Applicants note, however, that claim 3 is in independent form, and claims 4 and 80 depend, directly or indirectly, from claim 3. Thus, Applicants believe that the objection of claims 3, 4, and 80 was issued in error, and respectfully request that the Office allow these claims in a subsequent Office communication.

Claim Rejections Under 35 U.S.C. §112 (written description)

Claims 2, 5, 6, and 25 continue to be rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the invention at the time the application was filed. Claim 6 is canceled, rendering the rejection of this claim moot. Applicants traverse this rejection as it applies to claims 2, 5, and 25.

Solely to advance prosecution in this case, claim 2 is amended to be directed to “an amino acid sequence set forth as SEQ ID NO: 11.” In addition, claim 5 is amended to be directed to an “immunogenic fragment . . . wherein the immunogenic fragment comprises at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11, that specifically binds to an antibody that specifically binds the amino acid sequence set forth as SEQ ID NO: 11.” Support for the amendment of claim 5 can be found in the specification at least at page 36, lines 5-7.

As established in *Ex parte Parks*, “adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed” *Ex parte Parks*, 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that “[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384,231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g. *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”).”

In the current instance, Applicants had possession of the peptide sequence set forth in SEQ ID NO: 11 and immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11 (for example, at page 36, lines 5-7). In addition, it was well known to those

of skill in the art at the time the application was filed how to identify immunogenic epitopes of known sequences. For example, MHC binding peptide databases, such as the ProPred database (<http://www.intech.res.in/raghava/propred>), were available at the time the application was filed (Singh and Raghava, *Bioinformatics*, 17(12):1236-1237, 2001). ProPred is a graphical web tool which can predict which regions of a known antigenic protein sequence binds class II MHC molecules and this database could have been used to identify immunogenic epitopes in polypeptide fragments that are “at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11”. Thus, Applicants submit that a person of ordinary skill would have envisioned the claimed genus of immunogenic fragments, given the knowledge and level of skill in the art at the time the application was filed, the teachings of the specification, and the provision of SEQ ID NO: 11 itself.

In light of the above arguments and amendments, Applicants submit that claims 2 and 5 are sufficiently described by the specification and request that the rejection of these claims under 35 U.S.C. §112, first paragraph, be withdrawn. Claim 25 depends from amended claim 2, and incorporates all the limitations thereof. In light of the above amendments, Applicants respectfully request that this rejection of claims 2, 5, 6, and 25 be withdrawn.

Claim Rejections Under 35 U.S.C. §112 (enablement)

Claims 25 and 81 are rejected under 35 U.S.C. §112, first paragraph as allegedly the “specification does not reasonably provide enablement for a pharmaceutical composition.” The Office action states that the specification is “enabling for an immunogenic composition” (Office action at page 8). Solely to advance prosecution in this case, claims 25 and 81 are amended to be directed to an “immunogenic composition.” Support for the amendment of claims 25 and 81 can be found in the specification at least at page 80, lines 1-12. In light of the amendment of claims 25 and 81, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections Under 35 U.S.C. §102

Claims 2, 5-6, and 77-79 are rejected as allegedly anticipated under 35 U.S.C. §102(b) by Jacobs *et al.* (WO9920644; published April 29, 1999). As discussed above, claims 6 and 77-79

are canceled, rendering the rejection of claims 6 and 77-79 moot. Applicants respectfully traverse this rejection as it applies to claims 2 and 5.

Claims 2 and 5, as amended, are directed to:

- a) an amino acid sequence set forth as SEQ ID NO: 11 (claim 2);
- b) a conservative variant of the amino acid sequence set forth as SEQ ID NO: 11 (claim 2); or
- c) an immunogenic fragment comprising at least fifteen consecutive amino acids of the amino acid sequence set forth as SEQ ID NO: 11 (claims 2 and 5).

Jacobs *et al.* teaches an antigenic fragment of SEQ ID NO: 11 that is only eight amino acids long. As claims 2 and 5 are directed to immunogenic fragments comprising at least fifteen consecutive amino acids of SEQ ID NO: 11, Jacobs *et al.* does not and cannot anticipate claims 2 and 5. In light of the above arguments and amendments, Applicants respectfully request that this rejection of claims 2 and 5 be withdrawn.

Request for Examiner Interview

Applicants believe the application is in condition for allowance and such action is requested. Examiner Archie is formally requested to contact the undersigned prior to issuance of an allowance in order to arrange a telephonic interview to discuss *rejoinder of withdrawn claims*. If an additional rejection is asserted, or if the present rejection is maintained, Examiner Archie is also formally requested to contact the undersigned in order to arrange a telephonic interview prior to issuance of the next Office action. It is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP §713.01, which indicates that an interview can be arranged in advance by a written request.

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the number listed below.

Respectfully submitted,

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